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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/044,842

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7921

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EXAMINER

JASTRZAB, KRISANNE MARIE

ART UNIT

PAPER NUMBER

1744

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/044,842

**Applicant(s)**

RAAD ET AL.

**Examiner**

Krisanne Jastrzab

**Art Unit**

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 35,69,74-77,91-111 and 114-134 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 35,69,74-77,91-111 and 114-134 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 05/07.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 69, 74-77, 91-111 and 114-134 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly claimed ranges of applicable molar ratios are not properly supported in the original disclosure because those ranges were not clearly identified therein.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shlenker et al., U.S. patent No. 5,965,276.

Shlenker et al., teach an antiseptic compound that preferably includes gentian violet and can include other biocides such as chlorhexidine. Shlenker et al., clearly teaches the binding capacity of gentian violet and combination thereof with other binding biocides and it would have been obvious to one of ordinary skill in the art that a combination of gentian violet and chlorhexidine would intrinsically achieve a bound

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biocide. See column 5, lines 5-15, column 6, lines 10-18 and column 16, lines 16-30 and columns 17-21.

Claims 69, 74-77, 91-93, 95-96, 99-100, 103-107, 109-111, 114-119, 121-122 and 124-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shlenker et al., '276.

Shlenker et al., teach biocidal compounds for application to a plurality of surfaces, both organic and inorganic, with a component of the compound being an indicative compound. Shlenker et al., teach the preferred use of gentian violet in combination with another biocide with chlorhexidine being preferred. The compound is applicable to polymeric medical devices including catheters, tubes, shunts and gloves, and is capable of disinfecting fluids and wounds as occurring in accidental sticks of medical workers and condom breaches. Shlenker et al., further lists a plurality of dyes that have biocide activity that can be incorporated into the compound including D&C Green No. 6, D&C Red 17, FD&C Yellow No.'s 5 and 6 and FD&C Blue No., and additional biocides such as triclosan. Shlenker is silent as to applicable molar ratios of compound components, however, it would have required mere routine experimentation to determine applicable ratios of the known components taught in Shlenker et al. It is further noted that the newly claimed molar ratio ranges fail to find proper support in the original disclosure, which disclosure, in fact, emphasizes that essentially any given ratio is acceptable, lacking any criticality. See column 1, lines 35-50, column 4, lines 6-50, column 5, lines 5-15, column 6, lines 10-18, column 7, lines 54-60, column 9, lines 20-25 and columns 17, line 20 through column 21, line 35.

With respect to claims 75-77, Shlenker et al., clearly teach the treatment of fluids and it would have been well within the purview of one of ordinary skill in the art to apply that treatment to any fluid in need of disinfection.

With respect to claims 91-93, Shlenker et al., teach the claimed materials. See column 4, lines 35-50.

With respect to claim 134, Shlenker et al., discloses and intra gastric nasal tube which would intrinsically place the compound in contact with a mucosal surface.

Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shlenker et al., as applied to claims 69, 74-77, 91-93, 95-96, 99-100, 103-107, 109-111, 114-119, 121-122 and 124-134 above, and further in view of Dangman et al., U.S. patent No. 5,335,373.

Dangman et al., teach polymeric medical gloves which constitute hospital equipment, which are constructed to contain an admixed antiseptic and dye composition which is applied to both the inorganic surface of the glove as well as the organic surface of the user's hand when the glove is punctured. The composition can include dyes such as FD & C Yellow No.s 5 and 6 or FD & C Blue No. 2, and antiseptics such as chlorhexidine, chloroctoxynol and triclosan and the components of the gloves can be from inorganic materials such as polymers or organic materials such as silk fibers. See column 19, lines 30-56, column 22, lines 20-60 and column 28, lines 35-56.

It would have been obvious to apply the compound of Shlenker et al., to the conventional glove construction taught in Dangman et al., including silk fibers because

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the common goal in both references is to provide antibacterial protection to both gloved workers and patients.

Claims 97, 101-102, 108, 120 and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shlenker et al., as applied to claims 69, 74-77, 91-93, 95-96, 99-100, 103-107, 109-111, 114-119, 121-122 and 124-134 above, and further in view of either Williford U.S. patent No. 5,261,169 or Dow, Jr. U.S. patent No. 5,120,325.

Both Williford and Dow, Jr. teach the known and expected functional equivalence of the biocidal dyes gentian violet and brilliant green in applications both directed to body and organic surface contact. See column 10, lines 13-30 of Williford and column 4, lines 30-68 of Dow, Jr.

It would have been obvious to one of ordinary skill in the art to substitute brilliant green for the gentian violet taught in Shlenker et al., because of their recognized functional equivalence as evidenced by both Williford and Dow, Jr.

Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shlenker et al., in view of either Williford or Dow, Jr. as applied above.

It would have been obvious to one of ordinary skill in the art to substitute brilliant green for the gentian violet taught in Shlenker et al., because of their recognized functional equivalence as evidenced by both Williford and Dow, Jr. Shlenker is silent as to applicable molar ratios of compound components, however, it would have required mere routine experimentation to determine applicable ratios of the known components taught in Shlenker et al. It is further noted that the newly claimed molar ratio ranges fail

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to find proper support in the original disclosure, which disclosure, in fact, emphasizes that essentially any given ratio is acceptable, lacking any criticality.

### ***Response to Arguments***

Applicant's arguments with respect to claims 35, 69, 74-77, 91-111 and 114-134 have been considered but are moot in view of the new ground(s) of rejection.

The Declaration filed 5/30/2007 is noted, however, is found insufficient to overcome the pending rejections. While effective activity is shown, synergistic activity outweighing that expected of the combination, is not.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Thurs. 6:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krisanne Jastrzab/  
Primary Examiner  
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August 17, 2007